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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,419	07/19/2001	Abdul Malik	0152.00396	6244

21901 7590 05/26/2004

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,419	MALIK ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2004 has been entered.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-6 and 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes in view of Ogden (full article newly cited and applied) or Sumpter. The Hayes reference teaches sol-gel chemistry-based Ucon-coated columns for capillary electrophoresis. A sol-gel chemistry-based novel approach for the preparation of a Ucon-coated fused-silica capillary column in capillary electrophoresis is presented. In this approach the sol-gel process is carried out inside 25 μm I.D. fused-silica capillaries. The sol solution contained appropriate quantities of an alkoxide-based sol-gel precursor, a polymeric coating material (Ucon), a crosslinking reagent, a surface derivatizing reagent, controlled amounts of water and a catalyst dissolved in a suitable solvent system. The coating procedure involves filling a capillary with the sol solution and allowing the sol-gel process to proceed for an optimum period. Hydrolysis of the alkoxide precursor and polycondensation of the hydrolyzed products with the surface silanol groups and the hydroxy-terminated Ucon molecules lead to the formation of a surface-bonded sol-gel coating on the inner walls of the capillary. The thickness of the coated film can be controlled by

varying the reaction time, coating solution composition and experimental conditions. Commercial availability of high purity sol-gel precursors (e.g., TEOS 99.999%), the ease of coating, run-to-run and column-to-column reproducibility, and long column lifetimes make sol-gel coating chemistry very much suitable for being applied in analytical microseparations column technology. Test samples of basic proteins and nucleotides were used to evaluate the column performance. These results show that the sol-gel coating scheme has allowed for the generation of biocompatible surfaces characterized by high separation efficiencies in CE. For different types of solutes, the sol-gel coated Ucon column consistently provided migration time R.S.D. values of the order of 0.5%. The experimental section of Hayes is identical or equivalent to page 22, lines 8-24 of the instant specification. Also figure 1 of Hayes is identical to figure 3 of the instant specification. In the first paragraph of the paper Hayes discusses the problems associated with fused-silica capillary columns cause by the adsorption of biomolecules with acidic silanol groups on the inner surface of the capillary. The last full paragraph of the left column of page 4 teaches several advantages of the sol-gel technique including the strong adhesion of the coating due to the chemical bond formed. The last paragraph of page 5 teaches the cleaning of the capillary followed by addition of the coating solution. The paragraph bridging the columns of page 6 discusses the factors that are responsible for the adsorption problem. Relative to the silanol groups Hayes teaches that a uniform distribution of the groups is necessary to achieve a uniform coverage of the chemically bonded organic coatings. The same paragraph teaches that untreated fused-silica capillaries are characterized by low concentrations and non-uniform distributions of these groups on the inner surface. This paragraph teaches that there is also the possibility for new silanol groups to be formed through reaction of the surface with atmospheric moisture. Consequently, chemical research into creation of silica surfaces with uniformly distributed silanol groups at their optimum concentration is fundamentally important for the overall development of column technology for capillary electrophoresis and other separation techniques. Important to the instant claims is the statement in this paragraph that a "silica surface with uniformly distributed silanol groups should be very much suited for its further chemical modification using various polymeric and monomeric reagents with functional groups that can react with silanol groups". Also in this paragraph is the statement that these "chemically bonded coatings will ensure effective coverage of the surface and reliably shield the

residual silanol groups to prevent their participation in solute adsorption phenomena." Hayes does not teach a hydrothermal treatment.

In the paper Ogden discusses characterization of fused-silica capillary tubing by contact angle measurements. The capillary rise method was used to obtain angle measurements on untreated fused silica and fused silica treated with a variety of deactivating reagents. The contact angle data were used in the construction of Zisman plots which allowed characterization of the wettability of the surfaces by their critical surface energies. The wettability of raw fused silica was found to be widely variable which adversely affects attempts to fully deactivate the surface. **Hydrothermal** treatment of the fused silica with HNO_3 was found to be adequate for cleaning and hydroxylating the surface so as to allow complete deactivation. Simple silylating reagents, cyclic siloxanes, and polysiloxanes covering a wide range of polarity were used and evaluated as deactivating reagents. On page 8 the first four full paragraphs are relevant to the instant claims in that they teach that for fused-silica, columns coated with a stationary phase without deactivation of the fused-silica surface will often exhibit undesirable activity toward the analytes. Ways of deactivating the surface and enhancing the wettability have been the focus of much research in capillary columns. The most satisfactory method of doing this is through chemical modification of the surface to replace the surface hydroxyl groups with silyl ether groups containing functional groups that are similar to or identical with those in the stationary phase. The paper looks at various hydrothermal and deactivation procedures and produces inert capillary gas chromatographic columns that have a high degree of surface coverage and are free of reversible and irreversible adsorption of nanogram levels of alcohols, amines and acids. The first two full paragraphs of page 14 compare the various procedures used to treat the columns including no treatment, rinsing and a hydrothermal treatment. Of note is the variability in the untreated columns and the incomplete deactivation of the columns when the columns are only rinsed compared to the completely deactivated surface when the columns are hydrothermally treated. This is again stated in the first full paragraph of page 16 in that the water and methanol rinses were not sufficient to remove whatever surface structure gave rise to the deactivation differences while the hydrothermal treatment was. The hydrothermal treatment was then characterized as "a necessary precaution to not only fully hydroxylate the surface but also to clean it."

In the paper Sumpter discusses static coating of 5 to 50 μm I.D. capillary columns for open tubular column chromatography. Dichlorofluoromethane, CCl3F, and Me4Si were used in the static coating of small diameter capillary columns (5 to 50 μm I.D.) to obtain highly efficient columns for gas and supercritical fluid chromatography. Capillary columns of 5-, 10-, 25-, and 50-μm I.D. were coated with stationary phase films of SE-33, SE-54, OV-215, 50% octyl, 45% phenoxypolyethyl ether, 50% liquid crystal, 25% biphenyl, 50% pentafluorophenyl, and 50% cyanopropyl polysiloxane stationary phases. Resultant evaluations of these columns in gas chromatography gave ~9000, 66000, 45000, and 19000 plates m^{-1}, respectively, for the different internal diameters. Important parameters which affect coating efficiency are identified and discussed in detail. Page 504 teaches that several preparation methods have been used for open tubular chromatography columns. Relative to the instant claims is the discussion of the chemical bonding method of coating the tubes. Page 506 teaches treating the columns prior to deactivation by a hydrothermal treatment and a dehydration treatment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the hydrothermal treatment of Ogden or Sumpter into the method of Hayes because of the recognized problem in surface coverage during the deactivation step as discussed by Hayes, Ogden and Sumpter and the ability of the hydrothermal treatment to produce a reproducible fully hydroxylated surface as taught by Ogden and the expectation taught by Hayes that a silica surface with uniformly distributed silanol groups should be very much suited for its further chemical modification using various polymeric and monomeric reagents with functional groups that can react with silanol groups and these chemically bonded coatings will ensure effective coverage of the surface and reliably shield the residual silanol groups to prevent their participation in solute adsorption phenomena.

4. The declaration filed on March 22, 2004 under 37 CFR 1.131 is sufficient to overcome the Wang reference.

5. The declaration filed on March 22, 2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Hayes reference. The Hayes reference is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131.

6. Applicant's arguments filed March 22, 2004 have been fully considered but they are not persuasive. As can be clearly seen from the expanded explanations above, examiner is not in any

manner relying on the disclosure of the Wang reference for the motivation behind the combination of Hayes with Ogden or Sumpter. It should be noted that the disclosure being relied on form the Hayes reference has not changed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited references are related to column preparation methods and columns made thereby. Examiner requests that applicant provide a copy of reference number 32 in the Hayes reference so that it can be considered since it appears to contain disclosure related to the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist

May 24, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER